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**WARNINGS AND PRECAUTIONS FOR
PECTUS SUPPORT BAR SYSTEM
ATTENTION OPERATING SURGEON**

DESCRIPTION

The Biomet Microfixation Pectus Support Bar and stabilizers are surgical implants intended to aid treatment of Pectus Excavatum deformity. The Pectus Support Bar provides the surgeon with a means to reposition bony structures (sternum, breastbone) by applying internal force outwardly eliminating the funnel shape deformity. The device should be removed when remodeling is evident.

MATERIALS

The Pectus Support Bar and stabilizers are made from Stainless Steel or Titanium.

INDICATION

Pectus Excavatum and other sternal deformities.

CONTRAINDICATIONS

1. Patients with mental or neurological conditions who are unwilling or incapable of following instructions.
2. Patients presenting metal sensitivity reactions.
3. Patients with insufficient quantity or quality of bone or fibrous tissue to allow remodeling.
4. Infection

WARNINGS AND PRECAUTIONS

The Pectus Support Bar provides the surgeon with a means of treating Pectus Excavatum, funnel chest, a congenital deformity often accompanied by shortness of breath in children. The device is not intended to replace chest wall structures. While the device is intended to expand the chest wall cavity eliminating the features of the deformity, the degree of initial reshaping and permanent remodeling for each case cannot be predetermined.

The surgeon is to be thoroughly familiar with the implants and the surgical procedure prior to surgery. The correct selection and placement of the implant is important. Preoperative planning to determine the most appropriate size and final position of the implant is required. The surgeon should avoid sharp bends, reverse bends, or bending the device at a hole. The implant can become dislodged, shift, or flip as a result of improper device selection, improper stabilization, not suturing the device(s), or patient activity too soon after surgery. Even though the implant is mechanically fixed (sutured) in position, care is to be taken to assure that the device is rigidly in apposition to the area of the deformity, as demonstrated by total or partial elimination of the visible deformity. If the deformity is not partially eliminated, a secondary Pectus Support Bar may be required or an alternative method of treatment is to be considered. During the course of the surgical procedure, and during implantation, extreme care is to be taken to avoid contact with the heart and lungs with either the implant or instruments, as contact to these organs can cause death or permanent injury to the patient. When considering removal, the surgeon should weigh the risks versus benefits when deciding when to remove the implant. Where evidence of adequate remodeling is present, removal should be performed. Implant removal is to be followed by post operative monitoring to check for reoccurrence of the deformity. Where reoccurrence is encountered, a secondary treatment or alternative treatment may be necessary.

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been even momentarily placed in a different patient.

PATIENT WARNINGS

Post operative care and monitoring is important. Metallic fixation devices cannot withstand activity levels and loads equal to those placed on a normal healthy chest wall. The implant can loosen, migrate, bend, or break as a result of weight bearing, load bearing, strenuous activity, or traumatic injury. The patient is to be warned by the operating surgeon to limit activities accordingly. Limitation of physical activities may be unique to each patient and the patient should be warned that noncompliance with post operative instructions could lead to complications described above. The patient must be made aware and warned that the deformity or some degree of deformity may be present even after treatment. In addition, the patient is to be warned of general surgical risks and possible adverse effects as listed, prior to surgery.

POSSIBLE ADVERSE EFFECTS

1. Metal sensitivity reactions or allergic reaction to the implant material.
2. Pain, discomfort, or abnormal sensation due to the presence of the device.
3. Surgical trauma; permanent or temporary nerve damage, permanent or temporary damage to heart, lungs, and other organs, body structures or tissues.
4. Skin irritation, infection, and pneumothorax.
5. Fracture, breakage, migration, or loosening of the implant.
6. Inadequate or incomplete remodeling of the deformity or return of deformity, prior to or after removal of implant.
7. Permanent injury or death.

CLEANING

Prior to sterilization, all implants must be carefully cleaned and inspected. It is important to confirm that implants which are returned for processing from the operating room have not entered the operative site, as they may have been compromised. Implants in the tray which have touched the defect or entered the operative site, should be discarded. Cleaning should be performed by trained medical personnel. For additional cleaning information, contact Biomet Microfixation Regulatory Affairs department fax 904-741-9425.

STERILITY

Steam sterilize the Pectus Support Bar prior to implantation using steam sterilization equipment which has been properly validated. Following is a recommended minimum cycle for steam sterilization that has been validated by Biomet Microfixation under laboratory conditions. Individual users must validate the cleaning and autoclaving procedures used on-site, including the on-site validation of recommended minimum cycle parameters described below.

Pre-vacuumed Steam Sterilization (Hi-VAC) Wrapped:

Temperature: 270 ° Fahrenheit (132° Celsius)

Time: Four (4) minutes

Drying Time: Thirty (30) minutes MINIMUM

Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in a particular health care facility. Testing should be conducted in the health care facility to assure that conditions essential to sterilization can be achieved. Since Biomet Microfixation is not familiar with individual hospital handling methods, cleaning methods and bioburden, Biomet Microfixation cannot assume responsibility for sterility even though the guideline is followed.

MRI Information

The Pectus Bar Implant, Part #01-3717 is MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance environment. ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, Pennsylvania, 2005.

Non-clinical testing demonstrated that the Pectus Bar Implant, Part#01-3717 is MR-Conditional. A patient with this implant can be scanned safely immediately after placement under the following conditions:

Magnetic Field Interactions

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less.

MRI-Related Heating

In non-clinical testing, the Pectus Bar Implant, Part #01-3717 produced the following temperature rises during MRI performed for 15-min in 1.5-Tesla (1.5-Tesla/64MHz, Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR2002B DHHS) and 3-Tesla (3-Tesla/128-MHz, Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI) MR systems, as follows:

Highest Temperature Change	MRI Condition
+2.5°C	1.5-T/64-MHz
+3.7°C	3-T/128-MHz

Therefore, the MRI-related heating experiments for the Pectus Bar Implant, Part#01-3717 at 1.5-Tesla and 3-Tesla using a transmit/receive RF body coil at MR system reported whole body averaged SARs of 2.4-W/kg (i.e., associated with a calorimetry value of 2.0-W/kg) and 2.5-W/kg (i.e., associated with a calorimetry value of 2.2-W/kg), respectively, indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than 2.5° C at 1.5-Tesla and 3.7° C at 3-Tesla.

Artifact Information

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Pectus Bar Implant, Part #01-3717. The artifact size information is, as follows:

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Vold Size	34,454-MM ²	20,670-mm ²	54,785-mm ²	17,877-mm ²
Imaging Plane	Parallel	Perpendicular	Parallel	Perpendicular

Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.

Operating Surgeons and all personnel involved with handling these products are responsible for attaining appropriate education and training within the scope of the activities with which they are involved in the handling and use of this product.

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